Protocol

Hip Resurfacing

(70180)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 11/17
Preauthorization	No	**Review Dates**: 07/12, 07/13, 07/14, 07/15, 11/15, 11/16	

Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With indication for hip replacement who would be expected to outlive a traditional prosthesis and have no contraindication for total hip resurfacing	Interventions of interest are: • Metal-on-metal total hip resurfacing device • Partial hip resurfacing device	Comparators of interest are: • Any traditional total hip arthroplasty device	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes • Health status measures • Quality of life • Treatment-related morbidity

Description

Hip resurfacing is an alternative to total hip arthroplasty (THA; also known as hip replacement) for patients with advanced arthritis of the hip. Total hip resurfacing (THR) describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in patients with painful hip joints. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head. Available prostheses are metal-on-metal devices.

Summary of Evidence

The evidence for hip resurfacing in young active patients who would potentially outlive a traditional total hip prosthesis includes two randomized controlled trials, numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The efficacy of THR performed with current techniques is similar to THA over the short to medium term, and THR may allow for easier conversion to a THA for younger patients who are expected to outlive their prosthesis. Based on potential ease of revision when compared with THA, the evidence available at this time supports the conclusions that hip resurfacing (partial or total) presents a reasonable alternative for active patients who are considered too young for THA, when performed by surgeons experienced in the technique. The literature on adverse effects such as metallosis, pseudotumor formation, and implant failure is evolving as longer follow-up becomes available. Due to the uncertain risk with metal-on-metal (MoM) implants, the risk-benefit ratio needs to be carefully considered on an individual basis. In addition, emerging evidence indicates an increased risk of failure in women, possibly due to smaller implant size. Therefore, these factors should also be considered in the overall patient evaluation

for THR, and patients should make an informed choice in conjunction with their treating physicians. The evidence is sufficient to determine quantitatively that the technology results in a meaningful improvement in the net health outcome.

Policy

Metal-on-metal total hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as an alternative to total hip replacement when the patient:

- Is a candidate for total hip replacement; AND
- Is likely to outlive a traditional prosthesis; AND
- Does not have a contraindication for total hip resurfacing (See Policy Guidelines).

Partial hip resurfacing with an FDA-approved device may be considered **medically necessary** in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet the following criteria:

- The patient is a candidate for total hip replacement; AND
- Is likely to outlive a traditional prosthesis; AND
- The patient has known or suspected metal sensitivity or concern about potential effects of metal ions; AND
- There is no more than 50% involvement of the femoral head; AND
- There is minimal change in acetabular cartilage or articular cartilage space identified on radiography.

All other types and applications of hip resurfacing are considered **investigational**.

Policy Guidelines

The FDA lists several contraindications for total hip resurfacing. These contraindications include (not a complete listing) the following:

- Bone stock inadequate to support the device due to:
  - severe osteopenia or a family history of severe osteoporosis or severe osteopenia
  - osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head
  - multiple cysts of the femoral head (more than one cm)
- Skeletal immaturity
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Known moderate to severe renal insufficiency
- Severely overweight
- Known or suspected metal sensitivity
- Immunosuppressed or receiving high doses of corticosteroids
- Females of child bearing age due to unknown effects on the fetus of metal ion release.

A 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems. The FDA advises that a metal-on-metal hip implant should be selected only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system. Factors to consider include the patient's age, sex, weight, diagnosis, and activity level. Patients should be informed about the benefits and risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Patient expectations and the potential complications of surgery with a metal-on-metal hip implant should be discussed.

Background

Hip resurfacing is an alternative to THA for patients with advanced arthritis of the hip. THR describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in patients with painful hip joints. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head. Hip resurfacing may be considered an alternative to THA, particularly in young active patients who would potentially outlive a total hip prosthesis. THR, investigated in a broader range of patients including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis, may be considered an alternative to THA, particularly in young active patients who would potentially outlive a total hip prosthesis. Therefore, hip resurfacing could be viewed as a time-buying procedure to delay the need for a THA. Proposed advantages of THR compared with THA include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a THR, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared with THA.

THR has undergone various evolutions over the past several decades, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of THR have been composed of polyethylene. However, over the years it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal (MoM) chromium and cobalt implant components are of increasing concern.

In January 2013, the U.S. FDA issued a safety communication on MoM hip implants (both THA and THR). FDA has provided updated safety information and recommendations to patients and health care providers. This new information is based on FDA's current assessment of MoM hip implants, including the benefits and risks, the evaluation of the published literature, and the results of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting. As of January 2013, FDA stated that it had insufficient scientific data to specify a concentration of metal ions in a patient's body or blood that would produce adverse systemic effects. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles.

Regulatory Status

In May 2006, the Birmingham Hip Resurfacing system was approved by FDA through the premarket approval (PMA) process for use in patients requiring primary hip resurfacing arthroplasty for noninflammatory or inflammatory arthritis. This decision was primarily based on a series of 2385 patients who received this device by a single surgeon in England. A number of postapproval requirements were agreed to, including the following items:

- Study longer term safety and effectiveness through 10-year follow-up of the initial 350 patients in the patient cohort that was part of the PMA.

- Study the "learning curve" and the longer term safety and effectiveness of the BHR in the United States by studying 350 patients at up to eight sites where clinical and radiographic data will be assessed annually through five years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at one, four, and 10 years.
- Implement a training program to provide clinical updates to investigators.

In 2007 and 2009, respectively, the Cormet™ Hip Resurfacing System (Corin) and the Conserve® Plus (Wright Medical Technology), MoM total hip resurfacing systems, were approved by FDA. The approval order for the Cormet system states that the device is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients having the following conditions: (1) noninflammatory degenerative arthritis such as osteoarthritis and avascular necrosis; (2) inflammatory arthritis such as rheumatoid arthritis. The Cormet Hip Resurfacing System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional THA due to an increased possibility of requiring ipsilateral hip joint revision.

Various devices have been cleared for marketing by FDA through the 510(k) process for partial hip (femoral) resurfacing. Some surgeons may be using a femoral resurfacing component together with an acetabular cup (total arthroplasty component) as an "off-label" application.

In January 2013, FDA issued a safety communication on MoM hip implants (including both hip resurfacing and hip replacement). FDA stated that MoM hip implants have unique risks in addition to the general risks of all hip implants.

- With MoM implants, some tiny metal particles wear off of the device around the implant, which may cause damage to bone and/or soft tissue surrounding the implant and joint.
- Some of the metal ions released will enter the bloodstream and travel to other parts of the body, where they may cause symptoms or illnesses elsewhere in the body (systemic reactions).

At present FDA does not have enough scientific data to specify the concentration of metal ions in a patient's body or blood necessary to produce adverse systemic effects. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles.

PMA product code: NXT.

Related Protocol

Surgical Treatment of Femoroacetabular Impingement

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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